K112434
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510(K) Summary of Safety and Effectiveness

Date Prepared: 23 August 2011

SEP 29 2011

1. **Submitted By:**

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2. **Device Name:**

Trade Name:	BD Oral/Enteral Syringe with BD UniVia Connection
Common Name:	Gastrointestinal tubes and accessories
Classification Name:	Tube, Feeding
Classification:	Class II, 21 CFR 880.5980

3. **Predicate Device:**

Trade Name:	Children's Medical Ventures Oral/Enteral Syringe
Manufacturer:	Children's Medical Ventures
510(k) Number:	K100099
Trade Name:	Becton Dickinson Single Use, Hypodermic Syringe
Manufacturer:	Becton, Dickinson and Comoany
510(k):	K980987
Trade Name:	BD Oral Syringe
Manufacturer:	Becton, Dickinson and Comoany
510(k):	Class I Exempt

4. **Device Description:**

The BD Oral/Enteral Syringe with BD UniVia Connection is a standard piston, syringe which incorporates a safety connector that is incompatible with luer (6%) connectors and intravenous devices. The BD Oral/Enteral Syringe with BD UniVia Connection is designed to mate with a range of enteral feeding extension sets. The 3-piece design syringe consists of a polypropylene barrel and plunger rod and a synthetic rubber stopper. In addition, the plunger rod of the BD Oral/Enteral Syringe with BD UniVia Connection incorporates an orange colorant to further distinguish the device from a standard piston, syringe. The performance of the BD Oral/Enteral Syringe with BD UniVia Connection is equivalent to the predicate device.

5. **Intended Use**:

The BD Oral/Enteral Syringe with BD UniVia Connection are intended to be used by healthcare professionals to measure and administer oral medication and enteral nutrition.

6. **Technological Characteristics:**

As compared to the predicate device, the principal device of this 510(k) premarket notification:

a) Operates under the same operating principle as the predicate device
b) Has the same barrel, plunger rod and stopper materials as the Becton, Dickinson Single Use Hypodermic Syringe predicate device.
c) Has the same barrel, plunger rod and stopper design used in the Becton, Dickinson Single Use Hypodermic Syringe predicate device with the exception of the safety connector
d) Has a similar non-luer connector as the Children's Medical Ventures Oral/Enteral Syringe, with the same design intent
e) Meets the requirements of ISO 7886-1 and ISO 7886-2 respectively with the exception of the safety connector feature
f) Meets the requirements of ISO 10993 as applicable to the intended use of the device
g) Is sterilized to the same sterilization assurance level (SAL) as the predicate device
h) Demonstrated equivalent performance to the predicate devices during design verification testing.

7. **Performance:**

Design Verification tests were performed based on the risk analysis and product requirements, and the results of these tests demonstrate that the BD Oral/Enteral Syringe with BD UniVia connection performed in an equivalent manner to the predicate devices and is safe and effective when used as intended. Design Verification tests for unique BD Oral/Enteral Syringe with BD UniVia Connection performance elements include:

Item#	Performance Specification:	Status of BD Oral/Enteral Syringe:
1	Tip Cap Leakage	Equivalent performance to predicates
2	Connection w/ Mating Devices	Equivalent performance to predicates
3	Luer Incompatibility	Equivalent performance to predicates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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SEP 2 9 2011

Re: K112434
Trade/Device Name: BD Oral/Enteral Syringe with BD UniVia Connection
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: August 23, 2011
Received: August 24, 2011

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112434

Device Name: BD Oral/Enteral Syringe with BD UniVia Connection

Indications for Use:

The BD Oral/Enteral Syringe with BD UniVia Connection are intended to be used by healthcare professionals to measure and administer oral medication and enteral nutrition.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112434